Paper No. 15

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte HAI-HANG KUO, CAROL A. MILLER,
DAYAWEERA WIJESURIYA, MEITAK TERESA YIP, and CHRIS T. ZIMMERLE

Appeal No. 2001-1392
Application No. 08/900,586

ON BRIEF

Before SCHEINER, ADAMS, and MILLS, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-13, which are all the claims pending in the application.

Claim 1 is illustrative of the subject matter on appeal and is reproduced below:

1. A method for determining the concentration of an analyte in a sample of body fluid which comprises the steps of:

a) providing a test matrix in the form of a strip through which the fluid sample can flow by capillarity, said strip having a first region which contains mobile specific binding partner for the analyte which binding partner bears a visually detectable label and can react with the analyte to form an analyte/labeled binding partner complex, at least one second region which contains immobilized analyte or an immobilized binding partner which is specific for an epitope of the analyte different than that to which the labeled binding partner is specific, at least one third region which contains means for capturing the analyte/labeled specific binding partner complex which is not bound in the second region and a fourth region which contains means for colorimetrically producing a visually detectable signal the intensity of which corresponds to the level of a second analyte in the sample of body fluid whose concentration is clinically related to that of the first analyte whose concentration is being determined;

b) developing the matrix by applying a sample of body fluid suspected of containing the first and second analytes thereto thereby allowing it to contact the labeled specific binding partner so that analyte present in the fluid sample binds to the labeled specific binding partner to form a complex while leaving excess, unreacted labeled binding partner free to further react whereby the fluid sample carries the analyte/labeled binding partner complex and unreacted labeled binding partner along the matrix by capillarity to the second region containing the immobilized analyte in which region unreacted labeled binding partner is bound to the immobilized analyte in inverse relationship to the concentration of the first analyte in the fluid test sample or the analyte /labeled specific binding partner complex is bound to the immobilized specific binding partner in a direct relationship to the concentration of first analyte in the fluid test sample; and the labeled specific binding partner which did not bind to the second region is carried by capillarity to the third region where it is immobilized by the immobilization means;

c) reading the second region of the developed matrix on a reflectance meter having a detector capable of measuring the visible signal from the visually detectable label to determine the concentration of the visually labeled binding partner in the second zone and reading the third zone of the developed strip in a similar manner to determine a signal from the labeled binding partner in the third zone of the matrix;

d) determining the final response signal by ratioing the signals from the labeled binding partner captured in the second region and the labeled binding partner immobilized in the third region;

e) determining the concentration of the first analyte in the fluid sample by comparing the final response signal determined in step d with final response signals determined in a similar manner for fluid samples containing known concentrations of the first analyte; and

f) correcting the concentration of first analyte as determined in step e by determining the concentration of the second analyte in the fluid test sample by measuring the intensity of the signal in the fourth region of the strip using a reflectance meter and then determining the ratio of the second analyte to the first analyte whose quantitative concentration is being sought.

The references relied upon by the examiner are:

Besch et al. (Besch)	3,615,229	Oct. 26, 1971
Baker et al. (Baker)	5,500,350	Mar. 19, 1996
Yip et al. (Yip)	5,385,847	Jan. 31, 1995

GROUND OF REJECTION

Claims 1-13 stand rejected under 35 U.S.C. § 103 as being unpatentable over Baker in view of Besch and further in view of Yip.

We reverse.

DISCUSSION

According to the examiner (Answer[1], page 4) the Baker method "comprises determining the concentration of an analyte or analytes in a sample of body fluid by providing a device for performing immunoasssays … through which a fluid sample can flow by capillarity." The examiner finds (Answer, bridging sentence, pages 4-5) that Baker discloses the use of a device and method "for measuring the ratio of the concentrations of two analytes … in a urine sample." While the examiner recognizes (Answer, page 5) that "[t]he claimed invention is … a method of determining the concentrations of multiple analytes in a sample, … using the ratio of control analytes … [to normalize] the concentration of a specific target analyte," the examiner fails to mention that Baker does not disclose such a method.

To overcome the deficiency in Baker, the examiner relies on Besch and Yip. According to the examiner (id.) Besch disclose an assay method to determine "the concentration of two analytes in urine (creatinine and estriol), with the determination of creatinine levels providing an analyte/creatinine ratio." The examiner finds (id.) that the Yip method "determines the concentration of proteins and creatinine with subsequent determination of protein/creatinine ratios to normalize urine concentrations of protein analytes in urine samples…." Therefore the examiner concludes (id.) "[t]he claimed invention appears to be an obvious variation of the reference teachings of determining the concentration of two analytes in fluids then normalizing the first analyte using the concentration of the second analyte."

[1] Paper No. 12, mailed July 20, 1999.

In response appellants argue (Brief[2], page 6) "[w]hile the [e]xaminer has correctly characterized the teachings of the cited references, it is not believed that these teachings fairly establish a case for prima facie obviousness for the present invention." We agree. As appellants explain (Brief, page 8) it is not "the concept of ratioing the concentration of one analyte to another [that] is patentable or even novel," instead it is appellants' invention taken as a whole that is novel and unobvious in view of the prior art relied upon. According to appellants (id.) [t]he teachings by Baker et al[. and Besch] of a basic ratioing technique is not suggestive of the claimed invention … [and the Yip] "method for measuring analyte to creatinine ratios … is completely different from that of the present claims."

In response to appellants' arguments the examiner simply restates his original conclusion (Answer, page 7) "the claimed invention appears to be an obvious variation of the reference teachings of determining the concentration of two analytes in fluids then normalizing the first analyte using the concentration of the second analyte." We remind the examiner, as set forth in In re Kotzab, 217 F.3d 1365, 1369-70, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000):

> A critical step in analyzing the patentability of claims pursuant to section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. … Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher."
>
> …

[2] Paper No. 11, received May 7, 1999.

> Most if not all inventions arise from a combination of old elements. … Thus, every element of a claimed invention may often be found in the prior art. … However, identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention. … Rather, to establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant. [Citations omitted].

On reflection, the examiner has at best established that individual parts of the claimed invention were known in the prior art. What is missing, however, is evidence that a skilled artisan, with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed. "[A] rejection cannot be predicated on the mere identification … of individual components of claimed limitations. Rather particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed." Ecolochem Inc. v. Southern California Edison, 227 F.3d 1361, 1375, 56 USPQ2d 1065, 1075-76 (Fed. Cir. 2000).

Thus we find the examiner has failed to provide sufficient evidence to support a prima facie case of obviousness of a method of determining the concentration of an analyte in a sample that uses the ratio of control analytes to normalize the concentration of a specific target analyte. We also find that the examiner fails to provide appropriate evidence that a test matrix having the attendant structure required by step a) of claim 1, would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made. We note that the

examiner fails to address the structure of the test matrix as set forth in step a) of claim 1.

In our opinion, the examiner failed to meet his burden[3] of establishing a prima facie case of obviousness. If the examiner fails to establish a prima facie case, the rejection is improper and will be overturned. In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). Accordingly, we reverse the rejection of claims 1-13 under 35 U.S.C. § 103 as being unpatentable over Baker in view of Besch and further in view of Yip.

REVERSED

Toni R. Scheiner	)
Administrative Patent Judge	)
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	)
	) BOARD OF PATENT
Donald E. Adams	)
Administrative Patent Judge	) APPEALS AND
	)
	) INTERFERENCES
	)
Demetra J. Mills	)
Administrative Patent Judge	)

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[3] In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992).